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Documentation for Laboratory Results

Laboratory 19 – Measles, Rubella, and Varicella

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(2) Documentation File Name-Laboratory 19 – Measles, Rubella, and Varicella

(3) Survey Years Included in this File Release-2001-2002

(4) Component Description

4.1 Measles

Measles is a highly infectious disease targeted for elimination in the United States by the year 1996. The elimination strategy called for vaccination of all susceptible persons at age 12-15 months and at 4-11 years. NHANES will assess age-specific population immunity, taking into account vaccinees who never develop antibodies, persons who may lose immunity over time, and persons who are immune from natural disease. The U.S. measles elimination goal for 1996 came at a time when measles elimination was being considered as an achievable goal worldwide by the World Health Organization. If success can be demonstrated in the U.S. as well as other countries in the hemisphere, worldwide efforts to eliminate measles will be encouraged. The benefit from a study of measles seroprevalence will be to document age-specific immunity that is found following measles elimination efforts and to help judge the levels of immunity that are needed to eliminate measles.

4.2 Rubella

Congenital rubella syndrome (CRS) is the term used to describe the serious birth defects that occur among infants born to women infected with rubella while pregnant. A single rubella vaccination, usually given as measles-mumps-rubella (MMR) vaccine, is thought to confer lifelong immunity. Widespread use of the vaccine has resulted in near elimination of CRS in the United States. In recent years, an increasing proportion of rubella cases have been reported among adults, and outbreaks have occurred among persons of Hispanic ethnicity.

Population-based rubella seroprevalence studies will provide valuable information about specific groups that lack rubella immunity and therefore could be targeted for immunization. Therefore serologic testing of NHANES

participants will be conducted to document the level of immunity to rubella by race and ethnicity and allow comparison data from NHANES III.

4.3 Varicella

In 1995, a vaccine for prevention of varicella (chicken pox) was licensed for use in persons 1 year of age and older. Wide use of the vaccine may change the epidemiology of the disease with a shift in incidence to older persons who are at higher risk than are younger persons for more severe disease and complications.

Older persons may have severe complications such as encephalitis and/or death if they develop varicella. Additionally, pregnant women can pass on varicella if they develop it in the last weeks of gestation with severe life-threatening consequences to the newborn. NHANES provides a unique opportunity to assess changes in the seroprevalence of immunity to varicella after introduction of the vaccine. Demographic data on immune and susceptible persons will help target vaccination programs toward groups at risk for disease.

(5) Sample Description:

5.1 Eligible Sample

Participants aged 6 to 49 years were tested.

(6) Description of the Laboratory Methodology

6.1 Measles, Rubella, and Varicella

The staff of the Immunoserology Unit of the California State Department of Health Services (CSDHS), Viral and Rickettsial Disease Laboratory (VRDL) developed these EIA tests. The procedures described below are the standardized protocols of the VRDL's in-house EIA tests for serodiagnosis of viral infections and are currently routinely used for the following viruses: adeno, cytomegalo, herpes simplex, influenza A and B, measles, mumps, rubella, parvo- B19, respiratory syncytial, St. Louis encephalitis, varicella-zoster, and western encephalitis. The individual steps in the test are the same for all these viruses, except that production and purification of viral and control antigens used in the assay are different for individual viruses. These assays are approved and routinely monitored by CLIA staff.

In the indirect EIA, a suitable antigen material (i.e., solubilized varicella-zoster virus) is coated on the wells of a 96-well microtiter plate, which is subsequently incubated with a diluted test specimen. If the specimen

contains antibody to the antigen, the antibody will form complexes with the antigen on the coated plate.
After washing unreacted serum components from the plate, an antibody-enzyme conjugate is added to the wells and incubated. The conjugate consists of antihuman IgG covalently coupled to the enzyme alkaline phosphatase. The conjugate will react with the antigen-antibody complex on the surface of the well resulting in a sandwich of well-antigen-antibody-antibody-enzyme. If the test specimen does not contain IgG antibody to the antigen, the conjugate will not bind to the well surface and will be removed by washing. The presence of enzyme in the complex is determined by adding an enzyme substrate (indicator system) to the well and incubating while a color reaction occurs. The enzyme substrate reaction will result in a yellow colored product, which is measured in a spectrophotometer adjusted to a wavelength of 405 nanometers with a side band adjusted to 630 nanometers.

(7) Laboratory Quality Control and Monitoring

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

(8) Data Processing and Editing

Blood specimens were processed, stored and shipped to Viral and Rickettsial Disease Laboratory, California State Department of Health Services, Berkeley, California for analysis. Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Description of the Laboratory Methodology section.

(9) Data Access:

All data are publicly available.

(10) Analytic Notes for Data Users:

10.1 The analysis of NHANES 2001-2002 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES2001-2002 Household Questionnaire Data Files contain demographic data, health indicators, and other related information

collected during household interviews. They also contain all survey design variables and sample weights for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

10.2 LBXRU-Rubella index

Rubella antibody data are reported both as an optical density index and in International Units. The index is calculated by subtracting the absorbance of the control well from the absorbance of the antigen well (AG-NS) and dividing the difference by the cut-off value. The cut-off value is calculated as the mean AG-NS value of duplicate 10 IU standards. The equation used is: O.D. index = (AG-NS)/Cut-off value

An LBXRU (O.D. index) greater than or equal to one indicates the presence of antibody.

10.3 LBDRUIU - Rubella International Units

Rubella antibody data are reported both as an optical density index and in International Units. International Units are calculated based on a standard curve using a regression analysis of duplicate AG-NS values of 10, 40, & 100 IU standards and their squares. An International Unit value greater than or equal to 10 is considered significant for Rubella.